



February 8, 2021

Medtronic Inc.
c/o Anupama Gaur, Ph.D.
Senior Regulatory Affairs Specialist
35-37a Cherry Hill Drive
Danvers, Massachusetts 01923-5186

Re: K120808

Trade/Device Name: Medtronic Vascular Export XT Catheter, Medtronic Vascular Export AP Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Dr. Gaur:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 07, 2012. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S Digitally signed by
Gregory W. O'connell -S
Date: 2021.02.08
08:18:32 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Medtronic Vascular
c/o Anupama Gaur, Ph.D.
Senior Regulatory Affairs Specialist
35-37A Cherry Hill Drive
Danvers, MA 01923

JUN - 7 2012

Re: K120808

Trade/Device Name: Export XT and Export AP Catheters
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: May 10, 2012
Received: May 11, 2012

Dear Dr. Gaur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

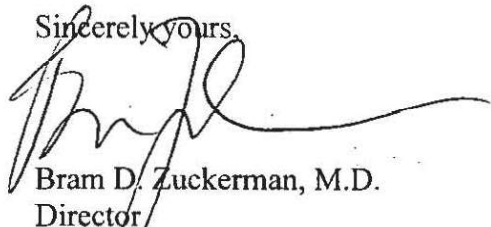
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: Medtronic Vascular Export XT & Export AP Catheters

Indications for Use:

- Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and
- To sub selectively infuse/deliver diagnostics or therapeutics agents with or without vessel occlusion.

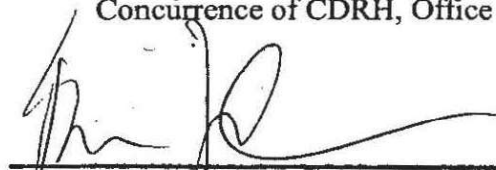
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K120808

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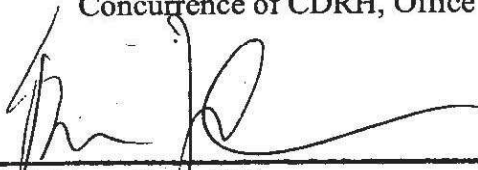
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Division of Cardiovascular Devices

510(k) Number K120808

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JUN - 7 2012

510(k) Summary

Submitter: Medtronic Vascular
35-37A Cherry Hill Drive
Danvers, MA 01923-5186

Contact Person: Anu Gaur
Senior Regulatory Affairs Specialist
Phone: (978) 739-3080
Fax: (978) 750-8204

Alternate Contact Fred Boucher
Director of Quality & Regulatory Affairs
Phone: (978) 739-3116
Fax: (978) 750-8204

Date Prepared: June 7th, 2012

Trade Name: Medtronic Vascular Export[®] XT Catheter
Medtronic Vascular Export[®] AP Catheter

Common Name: Percutaneous Catheter

Classification Name: Embolectomy Catheter
Class II per 21 CFR 870.5150, Product Code DXE

Predicate Devices: K061958 - Medtronic Vascular Export[®] XT Catheter
K081573 - Medtronic Vascular Export[®] AP Catheter

Device Description: The Export XT & Export AP Catheters are dual lumen catheters used for the aspiration of thrombus and/or debris from a vascular site. The Export XT & Export AP Catheters may also be used for the infusion of diagnostic or therapeutic agents to a desired vascular site.

Statement of Intended Use: Export XT & Export AP Catheters indications for use include:
- Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and
- To sub selectively infuse/deliver diagnostics or therapeutics agents with or without vessel occlusion.

Comparison to the predicate devices

A change in the processing aid (emulsifier) for the PTFE resin used for the microlumen tubing in the distal end of the catheter. The change replaces the PFOA emulsifier with a PFOA-Free emulsifier.

Summary of Technological Characteristics:

The modified Medtronic Export XT & Export AP Catheters involves the following features:

- i. Luer Hub
- ii. Strain Relief
- iii. Inner Liner
- iv. Braid Wire
- v. Proximal Shaft
- vi. Distal Shaft (Dual Lumen/Oversleeve)
- vii. Soft Tip
- viii. Microlumen (PTFE PFOA-Free)

Summary of Non-clinical Data:

The bench testing qualification and the biocompatibility testing for the material modification was conducted in accordance with the recommendations from the relevant FDA guidance to demonstrate that the proposed Export XT & Export AP Catheters have met the acceptance criteria and performed similarly to the predicate devices.

Bench Testing: The bench testing qualification was performed specific to the material change. The tests performed for bench testing included:

1. Shaft Stiffness Test.
2. Microlumen Wire Pull Through Test.

Biocompatibility Testing: Pursuant to the ISO 10993-1:2009 - *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*; and 21 CFR 58 - *Good Laboratory Practice for Nonclinical Laboratory Studies*; Medtronic Vascular has concluded full biocompatibility testing on the proposed device.

1. Cytotoxicity
2. *In vitro* Hemolysis
3. Systemic Toxicity
4. Sensitization
5. C3a Complement Activation
6. Sc5b9 Compliment Activation
7. ISO Intracutaneous Reactivity
8. USP Material Mediated Pyrogen Study
9. *In vivo* Thromboresistance

No new safety or effectiveness issues were raised during the

testing. The bench testing qualification and biocompatibility testing demonstrated that the proposed Export XT & Export AP Catheters devices are substantially equivalent to the predicate devices.

**Summary of
Clinical Data:**

No clinical investigation has been performed for these devices.

**Conclusion from
Data:**

Medtronic Vascular has demonstrated that the proposed Export XT & Export AP Catheters are substantially equivalent to the predicate devices.